

USE OF TRIPS FLEXIBILITIES TO INCREASE AFFORDABILITY OF TREATMENT FOR HIV, TUBERCULOSIS AND HEPATITIS C VIRUS IN MIDDLE-INCOME COUNTRIES

2023 ANNUAL REPORT OF 100% LIFE (January 1st to December 31st)

Name of the sub-grantee: A.O. «Positive Initiative»

Report submitted by: Serghei Craveti

Date of submission: 15.02.2024

SECTION I: Narrative & M&E

1. SUMMARY AND OVERALL ASSESSMENT (1 PAGE MAX)

Highlight key project milestones (if there are any), indicators achieved during the reporting period, (and explain any underachievement in expected milestones and indicators).

There were three key milestones during the reporting period:

- 1) The draft of amendments to the Law no. 50/2008 on the protection of inventions was approved by the Government and sent to the Parliament on 28.02.2023 and on 27.04.2023 was approved by the Parliament.
- 2) The process of drafting the new law on medicines commenced with the inclusion of Evghenii Golosceapov, a Civil Society expert on Human Rights and consultant for Positive Initiative, in the working group responsible for developing the draft legislation¹.
- 3) The ongoing court proceedings concerning the patent opposition related to Bedaquiline have entered a pivotal phase of activity.

Explain noteworthy (if there are any) changes in the grant's political/public health context that occurred during the reporting period.

In 2023, the Republic of Moldova experienced notable changes in both its political landscape and public health sector. One significant development was the country's designation as a candidate for EU country status, marking a pivotal step towards European integration. This designation signalled Moldova's commitment to aligning with EU standards and regulations, including those pertaining to public health. Concurrently, the initiation of the negotiation period had far-reaching implications, ushering in a period of dialogue and collaboration with EU stakeholders to negotiate terms of accession and reforms necessary for EU membership.

¹ <https://drive.google.com/file/d/1Ag7eufxyNNzFNPU2TD3WsnJKNCd3HalA/view?usp=sharing>

Describe your key priorities for the grant in the next six months. Please indicate for which medicines you plan to file patent oppositions or push for compulsory license in upcoming 6 months.

The grant priorities for the upcoming six-month period are outlined as follows:

- Continue Support for Bedaquiline Patent Opposition:
- Initiation of New Oppositions concerning the patents of Islatravir or Cabotegravir. This action will be guided by a comprehensive chemist's report assessing compliance with patentability conditions
- To further assist the National Agency for Medicinal Products and Medical Devices in their working process to formulate the new law on medicines. Emphasis will be placed on incorporating TRIPS flexibilities within this legislative framework, aligning with international standards and ensuring access to essential medicines.
- To Conduct market research and analysis on medical products, as well as prevention and diagnosis products.
- To conduct the analysis in order to identify and assess legal barriers hindering access to affordable medicines, particularly in light of Moldova's integration processes with the European Union (EU).

Summarize any key new opportunities you see and/or risks you see emerging and how would you address/mitigate it

There are several opportunities which might appear in the next 6 months:

- Efforts are underway to enhance and refine the amendments to the new law on medicines. A significant milestone in this process will be the publication of the draft law for public consultations;
- Court hearings on 31st of January 2024 on the submitted Bedaquiline patent opposition;
- The active engagement of the government in the EU integration process, coupled with efforts towards legislative alignment according to EU guidelines, offers a significant opportunity. This process provides a platform to incorporate TRIPS flexibilities into the new legislation, aligning national regulations with international standards and facilitating improved access to medicines.

There are following risks which might affect project implementation in the next 6 months.

- There remains a risk of a negative court verdict following the January 31 hearing regarding the Bedaquiline patent opposition. In the event of an unfavourable outcome, continued support for legal actions and heightened media coverage will be essential to exert public pressure on decision-making institutions, advocating for equitable outcomes.
- The accelerated pace of new law elaboration and adaptation poses a potential risk to the inclusion of critical amendments in the legislation. Rapid developments may hinder thorough consideration of important amendments, necessitating vigilant oversight and advocacy efforts to ensure that key provisions are adequately addressed in the final legislation.

2. PROGRAMMATIC PERFORMANCE

2.1 Output 1: Patent and Market Intelligence

What did you accomplish under Output 1? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress.

[Half page max. Please do not forget to describe what was the progress on the activities below that are from your hub workplan.]

1.2 Market and patent data collection, analysis and dissemination

During the reporting period, significant efforts were dedicated to conducting comprehensive analyses pertaining to various pharmaceutical and healthcare domains in the Republic of Moldova. Specifically:

Analysis of Cabotegravir and Islatravir Patents:

A detailed examination was undertaken to assess the availability of patents for Cabotegravir and Islatravir medications within the Republic of Moldova. This analysis aimed to ascertain the feasibility of initiating patent opposition proceedings through legal channels. This strategic approach seeks to ensure equitable access to these essential medicines while following intellectual property regulations.

Retrospective Procurement Analysis for COVID-19 Medications:

A retrospective analysis of drug procurement activities concerning the prevention and control of COVID-19 infection was conducted for the years 2020, 2021, and 2022. This comprehensive review provides insights into procurement practices, supply chain dynamics, and resource allocation strategies employed during the pandemic.

Retrospective Procurement Analysis within the National Cancer Control Programme:

In alignment with the National Cancer Control Programme, a retrospective procurement analysis spanning the years 2020, 2021, and 2022 was executed. This evaluation aims to assess the efficiency and effectiveness of procurement practices related to cancer treatment and care. By scrutinizing procurement activities within this critical healthcare domain, opportunities for improvement and optimization can be identified to enhance the delivery of cancer care services².

2.2 Output 3: Remove IP Barriers

What did you accomplish under Output 3? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress. [Half page max]

² https://drive.google.com/drive/folders/12vKicZ7L_ojMMxTDh4PdkNWptv_6Srdh?usp=sharing

3.1. Files patent challenges/legal interventions

During the reporting period, various activities were carried out to support the lawsuit over the Bedaquiline patent:

- In 2023, a new judge named Andrei Ozhoga took over the case after the previous judge's term ended.
- The first session happened on March 20, 2023. At this session, Judge Ozhoga looked over the case file. The defendant didn't show up, so the case was postponed.
- Throughout the reporting period, there were a total of 7 meetings³. Key points from these meetings include:

At the second meeting, Janssen Pharmaceutica attended but asked for more time to review the case documents. This delayed the case until later in the year.

In October, Janssen Pharmaceutica decided not to participate and requested the case be considered without them, prolonging the trial.

During the last hearing on December 11, 2023, Judge Ozhoga told everyone that he asked for more expertise from the National Agency for Intellectual Property.

The next hearing is scheduled for January 31, 2024, where AGEPI will present their arguments.

At the same time, during the reporting period, a comprehensive series of activities were carried out to prepare for the filing of a patent appeal application for Islatravir and Cabotegravir.

- Out of data collected, two HIV medicines were identified as prospective for further interventions in consultation with national partners: Islatravir, Cabotegravir;
- On June 27 a request for patent search on the above-listed medicines was submitted to the AGEPI, the request contained an information on 4 patents issued on these medicines and 1 patent application⁴;
- On July 27 AGEPI provided their reply with the list of patents in relation to the listed medicines⁵: 3 patents on Cabotegravir, 1 patent and 1 patent application on Islatravir;
- As a result, patents related to both medicines were identified as priority for further analysis and eventual elaboration of patent opposition. The patents were analysed by an expert chemist with the conclusion that all of them could be appealed against⁶.

By the end of the reporting period the analysis of the prioritised patents was completed by an expert in chemistry. The expert concluded that there are grounds for filing patents opposition questioning primarily the novelty of the inventions. The elaboration of patents opposition started at the end of the reporting period. The opposition is planned to be filed in the court of justice during the first half of 2024.

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

³ <https://drive.google.com/drive/folders/1qaLngvhIRIDKAC6PZzPf39uMslbjHyHv?usp=sharing>

⁴ https://drive.google.com/file/d/1Tnr7YMfK5lu7_MFqErMw9kFCFPj0Bx6G/view?usp=sharing

⁵ <https://drive.google.com/file/d/1zlyam-ccQPZ0yx-a7mEOSgkaW5VLIyY/view?usp=sharing>

⁶ <https://drive.google.com/drive/folders/12J8otLtveNQT-t00BQSupN8FtJVkCzlv?usp=sharing>

[Half page max]

2.3 Output 4: Create sustainable results and generate systemic, sustainable, replicable outcomes to move the market for ARVs, DAAs and TB medicines

What did you accomplish under Output 4? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress. [Half page max]

[Half page max. Please do not forget to describe what was the progress on the activities below that are from your hub workplan.]

4.1. Support national law and policy reform efforts for use of flexibilities

During the reporting period, significant decisions were made regarding National IP reform and the implementation of TRIPS flexibilities. The draft amendments to Law no. 50/2008 on the protection of inventions were approved by the Government and subsequently sent to Parliament on February 28, 2023. They were then approved by Parliament on April 27, 2023.

The key changes introduced to the Patents' Law encompass a variety of provisions, with approximately 60% deemed beneficial or potentially beneficial for increasing access to medicine for the population. Noteworthy amendments include the addition of the TRIPS notion to the law and the inclusion of the Bolar provision. Furthermore, specific provisions regarding compulsory licenses were expanded, allowing for court-issued licenses on grounds such as non-exploitation of patents, public interests, and combating anti-competitive practices.

Importantly, the law now allows for the issuance of compulsory licenses in cases of public health emergencies, aligning with TRIPS flexibility. However, certain aspects of the amendments, such as the calculation of fees for patent holders and the lack of protection for data and market exclusivity of pharmaceutical products when compulsory licenses are issued, pose challenges. Nonetheless, the amendments represent a step towards enhancing intellectual property regulations while balancing public health needs in the Republic of Moldova.

The draft law no. 50/2008 was approved; however, the elaboration of a new law on medicines has commenced. This new law presents an additional opportunity for the implementation of TRIPS flexibilities.

The process of drafting the new law on medicines began with the creation of the working group and appointment of Evghenii Golosceapov, a Civil Society expert on Human Rights and consultant for Positive Initiative, to the formed working group tasked with developing the draft legislation. Through collaborative efforts within the working group, Golosceapov's input played a pivotal role in shaping the provisions of the new law on medicines, ultimately striving to enhance healthcare access and delivery in the Republic of Moldova.

On September 18-20, 2023, Positive Initiative staff, in collaboration with experts in the field of Intellectual Property from Ukraine, held a three-day workshop at the Agency for Medicines and Medical Devices of Moldova on "Ensuring Patients' Access to Treatment: Drug Registration and Intellectual Property"⁷.

⁷ <https://drive.google.com/drive/folders/1wbNpeHUzUMbVQqRSjuG3X73IEA4fVTcl?usp=sharing>



<https://www.facebook.com/photo/?fbid=693272216165890&set=pcb.693272292832549>

The workshop was aimed at incorporating TRIPS flexibilities into the Agency's draft law on medicines.

This draft law is being elaborated in the context of harmonization of the legislation of the Republic of Moldova with the EU directives.

On October 26, 2023 another training meeting was held for the staff of the Agency for Medicines and Medical Devices of the Republic of Moldova⁸.

The main objective of the meeting was to increase the understanding of the Agency staff on the concept of "Parallel import of medicines" in the context of drafting a law on medicines in the Republic of Moldova.

On November 21, 2023, Positive Initiative took an active part in the public consultation on the draft of the new Law on Medicines. The event was organised by the Ministry of Health of the Republic of Moldova together with the Agency for Medicines and Medical Devices⁹. PI participants represented the interests of patients, focusing on the issues of drug registration and intellectual property. This important event was attended by key players in the pharmaceutical market, including the World Health Organization, the Pharmacists Association and others.

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

The implementation of planned activities faced several challenges during the reporting period. These challenges included navigating legislative complexities, fostering coordination and collaboration among stakeholders, and enhancing public engagement and awareness. To address these challenges, there is a further need to strengthen stakeholder engagement, enhance capacity-building efforts, increase public awareness, and establish robust monitoring of the law adoption processes. Additionally, addressing these challenges may require additional funding to support capacity-building initiatives, stakeholder engagement activities, and public awareness campaigns.

⁸ <https://drive.google.com/drive/folders/1g5jHnCBR0I811CeG4DqS8kAFTY8aG9Ee?usp=sharing>

⁹ https://amdm.gov.md/ro/news/lansarea-discu-iilor-publice-privind-noul-proiect-al-legii-medicamentelor?fbclid=IwAR1ZSMXk6NevlYqNy5Fd9LPaxVqhXIYQol_WZuM1P6es7DQCD1NwDS5spiM

2.4 Output 5: Amplifying visibility, coordination, effectiveness and support for the consortium's work

What did you accomplish under Output 5? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress.

[Half page max. Please do not forget to describe what was the progress on the activities below that are from your hub workplan.]

5.4 Development of PR-materials and publishing in media (Moldova)

Project and ITPC visibility were meticulously maintained throughout the organized events. Essential updates on the project's activities were prominently featured on the Facebook page of the Positive Initiative, as well as on its official website. Additionally, links to any press releases or noteworthy news items were thoughtfully included in the comprehensive report provided. This comprehensive approach ensured that stakeholders and interested parties remained well-informed and engaged with the project's progress.

- 1) Tuberculosis prevention is more effective with community-based specialists
<https://positivepeople.md/profilaktika-tuberkuleza-effektivnej-blagodarya-specialista-na-baze-soobschestv/>
- 2) Civil society calls for rejection of secondary patent on bedaquiline
<https://positivepeople.md/grazhdanskoe-obschestvo-prizyvaet-otkazatsiya-ot-vmorichnogo-patenta-na-bedakvilin/>
- 3) WHO chief in favor of creating council to accelerate development of new TB vaccines
<https://positivepeople.md/glava-voz-za-sozдание-soveta-po-uskoreniyu-razrabotki-novyh-vakcin-ot-tuberkuleza/>
- 4) How a pharmaceutical company made \$114 billion on evergreen patents
<https://positivepeople.md/kak-farmaceuticheskaya-kompaniya-zarabotala-114-mlrd-na-vechnozelenyh-patentah/>
- 5) Making medicines more accessible and cheaper. New Patent Pool Strategy
<https://positivepeople.md/povyshenie-dostupnosti-i-deshevizny-lekarstv-novaya-strategiya-patentnogo-pula/>
- 6) Trend towards shorter TB treatment timeframes
<https://positivepeople.md/tendenciya-na-sokraschenie-srokov-lecheniya-tuberkuleza/>
- 7) How do generics differ from original medicines? Why is there such a difference in price?
<https://positivepeople.md/chem-dzheneriki-otlichayutsya-ot-originalinyh-lekarstv-pochemu-takaya-raznica-v-cene/>
- 8) Down with evergreen patents: generics of Bedaquiline coming soon to India
<https://positivepeople.md/dolozh-vechnozelenye-patenty-skoro-v-indii-poyavyatsya-generiki-bedakvilina/>
- 9) U.S. pharma companies face a new "patent collapse." Why it's a good thing"
<https://positivepeople.md/amerikanskije-farmkompanii-zhdet-novyj-patentnyj-obval-pochemu-eto-horosho/>
- 10) NGOs advocate for the termination of pharmaceutical company Gilead's patents
<https://positivepeople.md/npo-vystupayut-za-prekraschenie-patentov-farmkompanii-gilead/>
- 11) How a secondary patent could deprive 6,000,000 people of a TB cure over the next few years!

- [https://www.facebook.com/initiativapozitiva/posts/pfbid02CVhKvBHzME68UT68Z1vkr9RQrtP5ELhiFMT8F8pCadURM3G6QRDW84ZwCwyJ1B71l? cft \[0\]=AZXLCZFYPZH6oYsqwU s5xUHj1fCZ6plQD9Elzi90osAiiFIOj580Z47Fx QRQ9BvFjUZyqi1w3GhHUOF2pHUOzDMiLcWj kmeGsOUGgKqVJhun8y88Be6xlgBJD2Ax1SV5DsxknkWSknxnBGNI-PfatYBT42YAjlw7TJli5Uz2uEuY0alfKxrRpsgnYPuOA67X4& tn =%2CO%2CP-R](https://www.facebook.com/initiativapozitiva/posts/pfbid02CVhKvBHzME68UT68Z1vkr9RQrtP5ELhiFMT8F8pCadURM3G6QRDW84ZwCwyJ1B71l? cft [0]=AZXLCZFYPZH6oYsqwU s5xUHj1fCZ6plQD9Elzi90osAiiFIOj580Z47Fx QRQ9BvFjUZyqi1w3GhHUOF2pHUOzDMiLcWj kmeGsOUGgKqVJhun8y88Be6xlgBJD2Ax1SV5DsxknkWSknxnBGNI-PfatYBT42YAjlw7TJli5Uz2uEuY0alfKxrRpsgnYPuOA67X4& tn =%2CO%2CP-R)
- 12) Millions of people will get cheaper TB drugs
<https://positivepeople.md/milliony-lyudej-poluchat-bolee-deshevye-lekarstva-ot-tuberkuleza/>
 - 13) Doctors Without Borders refused to sign an agreement with pharma company ViiV Healthcare
<https://positivepeople.md/vrachi-bez-granic-otkazalisi-podpisyvati-soglashenie-s-farmkompaniej-viiv-healthcare/>
 - 14) Global Fund strikes deal to lower HIV drug prices
<https://positivepeople.md/globalinyj-fond-zaklyuchil-sdelku-po-snizheniyu-cen-na-lekarstva-ot-vich/>
 - 15) Moldova against pharma monopoly: the choice between profit and health.
<https://positivepeople.md/moldova-protiv-monopolii-farmy-vybor-mezhdu-pribyliyu-i-zdoroviem/>
 - 16) Workshop "Ensuring patient access to treatment: drug registration and intellectual property"
[https://www.facebook.com/initiativapozitiva/posts/pfbid02m1a5sTNGUt11jKcE3EwgA8m vHArvc25cA7dAHgkyVE7wvrR7fNPQqZRHf2SKwXGQI? cft \[0\]=AZUKNmgoBwZjn8BfNst_CQz0sVOPW7bHMYI6Uw2V-g49XXt05w2fRX8wjUcVYx0gQEkCxb9kVY9IThFQooyKyXpuXGuQ97zHjkhTpGwPglra4OVpJf o6KP6iE77uRfBkpb5elCaiz9iKBITHfZBfyKIU9N5JbMtokD9cRAhAfvTBsPBkb7WWRDI3MlpZ QeRXM8& tn =%2CO%2CP-R](https://www.facebook.com/initiativapozitiva/posts/pfbid02m1a5sTNGUt11jKcE3EwgA8m vHArvc25cA7dAHgkyVE7wvrR7fNPQqZRHf2SKwXGQI? cft [0]=AZUKNmgoBwZjn8BfNst_CQz0sVOPW7bHMYI6Uw2V-g49XXt05w2fRX8wjUcVYx0gQEkCxb9kVY9IThFQooyKyXpuXGuQ97zHjkhTpGwPglra4OVpJf o6KP6iE77uRfBkpb5elCaiz9iKBITHfZBfyKIU9N5JbMtokD9cRAhAfvTBsPBkb7WWRDI3MlpZ QeRXM8& tn =%2CO%2CP-R)
 - 17) Availability of GeneXpert test for tuberculosis
[https://www.facebook.com/watch/?v=2464540723700476& cft \[0\]=AZVxVUFHXSou4n u0YNwdneXKaMSIjp4z4I Y56-2R-yYftS0oXIJt5FGN4LGDdkRvJz1RPVsEV UFcLuBeq0NPsuOsUzXQmT4KzSycDOHijxf3mDRV mQwggBkxKpRi5zITb8TQ6QJjipKYHDcyuuXi7jhH-Z82dukmuJWSpwgcnP1yzrjzboEggJvZl-gwtNE& tn =%2CO%2CP-R](https://www.facebook.com/watch/?v=2464540723700476& cft [0]=AZVxVUFHXSou4n u0YNwdneXKaMSIjp4z4I Y56-2R-yYftS0oXIJt5FGN4LGDdkRvJz1RPVsEV UFcLuBeq0NPsuOsUzXQmT4KzSycDOHijxf3mDRV mQwggBkxKpRi5zITb8TQ6QJjipKYHDcyuuXi7jhH-Z82dukmuJWSpwgcnP1yzrjzboEggJvZl-gwtNE& tn =%2CO%2CP-R)
 - 18) Cepheid and Danaher have reduced the price of GeneXpert TB, an effective test for tuberculosis
<https://positivepeople.md/cepheid-i-danaher-snizili-cenu-na-effektivnyj-test-na-tuberkulez-genexpert-tb/>
 - 19) Pharma company to pay \$246 million to settle generics delay lawsuit
<https://positivepeople.md/farmkompaniya-vyplatit-246-mln-dlya-uregulirovaniya-iska-ozaderzhke-dzhenerikov/>
 - 20) Meeting on expanding access to treatment and diagnostics for HIV, viral hepatitis and tuberculosis in Almaty
[https://www.facebook.com/initiativapozitiva/posts/pfbid02Q7nE4Es7XWjfe5dAGBQZQ1q afUVVJqD8N6e4gy1zcl7GYjrjMJXynap1CwgoceYPI? cft \[0\]=AZWxnst3BHKXvRvHToMzg geDC cNXhPJ1wYHFpQgsMHLjPYfnsHv6fWyhOIODjZ1QYNg d KuQCqmZI BJuCvH2mWBP z6kzaC U0eopLHUqKmaPkXp hoqukxMu6INNjRIZwWNbTfb9IPLe1Zyir4jipKE92oXlkGilv8n cO62Mzc36AmEyRtW LbrbmKvWoV8TcnImruACEod0whq-eVg& tn =%2CO%2CP-R](https://www.facebook.com/initiativapozitiva/posts/pfbid02Q7nE4Es7XWjfe5dAGBQZQ1q afUVVJqD8N6e4gy1zcl7GYjrjMJXynap1CwgoceYPI? cft [0]=AZWxnst3BHKXvRvHToMzg geDC cNXhPJ1wYHFpQgsMHLjPYfnsHv6fWyhOIODjZ1QYNg d KuQCqmZI BJuCvH2mWBP z6kzaC U0eopLHUqKmaPkXp hoqukxMu6INNjRIZwWNbTfb9IPLe1Zyir4jipKE92oXlkGilv8n cO62Mzc36AmEyRtW LbrbmKvWoV8TcnImruACEod0whq-eVg& tn =%2CO%2CP-R)
 - 21) Johnson & Johnson confirms the manufacture and supply of generic bedaquiline in low- and middle-income countries.
<https://positivepeople.md/johnson-johnson-podtverzhaet-proizvodstvo-i-postavku-generikov-bedakvilina-v-strany-s-nizkim-i-srednim-urovнем-dohoda/>
 - 22) Call on ViiV Healthcare to make injectable PrEP cheaper for Moldova, Georgia and others

<https://positivepeople.md/prizyv-k-viiv-healthcare-sdelati-deshevle-injekcionnyj-prep-dlya-moldovy-gruzii-i-dr/>

- 23) Participation in public consultations to promote the draft of the new Law on Medicines
[https://www.facebook.com/initiativapozitiva/posts/pfbid02F2mGqZrDLxSRLV7AGUk3bgd1rMY5cjXiMzKju3tdUcUg9u6YtLuqpRrS5zfXrh5HI?_cft__\[0\]=AZXauDL6K0WifV5tuZGOOJHv1P1xbF7Z4MuMuD1CAL5-O60sWRmJiTXn6FaXqkTX9HGRswUo8pocpNL8zNd874I_oJmBdxVCNUQLsm5AULY7CUNT_XpUa003OmtvqsOfjOJO1Pn1uek106ku04q3uSCfe7OIs8bRIC6EIWriR5HFBLzZxwV1mcgm2WYi1bBkWLfJSBsUXlwwFxlMp723OMr&_tn=%2CO%2CP-R](https://www.facebook.com/initiativapozitiva/posts/pfbid02F2mGqZrDLxSRLV7AGUk3bgd1rMY5cjXiMzKju3tdUcUg9u6YtLuqpRrS5zfXrh5HI?_cft__[0]=AZXauDL6K0WifV5tuZGOOJHv1P1xbF7Z4MuMuD1CAL5-O60sWRmJiTXn6FaXqkTX9HGRswUo8pocpNL8zNd874I_oJmBdxVCNUQLsm5AULY7CUNT_XpUa003OmtvqsOfjOJO1Pn1uek106ku04q3uSCfe7OIs8bRIC6EIWriR5HFBLzZxwV1mcgm2WYi1bBkWLfJSBsUXlwwFxlMp723OMr&_tn=%2CO%2CP-R)

24) Compulsory license for dolutegravir formally confirmed in Colombia
<https://positivepeople.md/prinuditelinaya-licenziya-na-dolutegravir-oficialno-podtverzhdena-v-kolumbii/>

- 25) A patent on an AI-designed drug: ownership and liability issues
<https://positivepeople.md/patent-na-lekarstvo-razrobotannoe-ii-voprosy-sobstvennosti-i-otvetstvennosti/>

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

The ongoing war in neighboring Ukraine continued to exert significant pressure on Moldova, with the influx of refugees adding strain to the country's resources and infrastructure. This humanitarian crisis diverted attention and resources away from health-related initiatives, including efforts to address intellectual property barriers.

Furthermore, Moldova grappled with an ongoing energy crisis and soaring prices of energy sources, exacerbating economic challenges and impacting the availability of funds for healthcare projects. The high rate of inflation, which persisted from the previous year, further strained the country's financial resources.

Moreover, the prevailing traditional mindset regarding intellectual property posed a persistent challenge. The perception of IP as a superior value compared to the right to health hindered efforts to implement projects aimed at overcoming IP barriers. Effective communication strategies were crucial in navigating these entrenched beliefs and garnering support for initiatives promoting equitable access to medicine.

3.

4. COMPLEMENTARY FINANCIAL INFORMATION

SECTION II: Financial Performance Narrative

Please fill in the following table:

Budget implementation	Reporting period			Grant start to reporting year end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget ¹⁰	Total expenditure to date	%
Proportion of budget spent	56112.12	56112.12	100	108790.89	108790.89	100

PLEASE NOTE THAT BELOW BUDGET NARRATIVE PART SHOULD BE REPEATED FOR EACH OUTPUT RIGHT AFTER RELEVANT OUTPUT NARRATIVE PARTS

Please fill in the following table:

	Reporting period			Grant start to reporting period end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 1:	0	0		0	0	

	Reporting period			Grant start to reporting period end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 2:	2160	2159.33	100	4206.08	4211.23	100

	Reporting period			Grant start to reporting period end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 3:	11279.24	11116.90	99	22880.26	22667.78	99

	Reporting period			Grant start to reporting period end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 4:	10845.68	10611.91	99	20697.58	20370.52	98

¹⁰ This is the cumulative budget from the start of the grant through the end of the current reporting year.

	Reporting period			Grant start to reporting period end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 5:	7700	7711.84	100	13439.75	13472.93	100

	Reporting period			Grant start to reporting period end		
	2023 budget	January to December 2023 expenditure	%	Cumulative budget	Total expenditure to date	%
Grant Management	24127.2	24512.14	102	47567.22	48068.43	101

Please provide comments on your financial performance for each output. Explain each variance (%)